

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEURONTIN MARKETING AND
SALES PRACTICES LITIGATION

MDL Docket No. 1629

Master File No. 04-10981

THIS DOCUMENT RELATES TO:

ALL ACTIONS

Judge Patti B. Saris

STIPULATED PROTECTIVE ORDER

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, the Court enters the following Protective Order (“Order”) limiting the disclosure of discovered information and limiting the use of such information as hereinafter provided. IT IS HEREBY STIPULATED AND ORDERED THAT:

1. This Order shall govern the treatment of pleadings, correspondence, legal memoranda, documents and other discovery materials, and any other information or written materials which have been or will be filed, exchanged, served, produced or received by the parties during pre-trial proceedings in the actions that have been assigned to the above captioned multi-district litigation, as well as any and all copies, abstracts and summaries (the “Discovery Materials”).

2. Definitions: As used herein, the following terms shall have the following meanings:

“The litigation” and “this litigation” shall refer to all actions that have been assigned to the above captioned Multi-District Litigation proceeding.

"The parties" shall refer to all of the parties in all of the actions that have been assigned to the above captioned Multi-District Litigation proceeding.

"Trade secrets" and "other confidential research, development, or commercial information" shall have the same meanings as such terms have been found to have in Fed.R.Civ.P. 26(c)(7).

"Individually identifiable health information" shall have the same definition as set forth in 42 U.S.C. § 1320d(6).

3. Scope.

(a) All documents and information furnished by a party in conjunction with this litigation which contain (i) trade secrets or other confidential research, development, or commercial information, or (ii) individually identifiable health information ("Confidential Information") may be designated CONFIDENTIAL by said party and furnished to the other parties pursuant to the terms of this Order. The party receiving designated Confidential Information shall treat it as proprietary information and shall not use or disclose the information except for the purposes set forth in this Order or such orders as may be issued by the Court during the course of this litigation. The provisions of this Order extend to all designated Confidential Information regardless of the manner in which it is disclosed, including but not limited to documents, interrogatory answers, responses to requests for admissions, deposition transcripts, deposition exhibits, and any other discovery materials produced by a party in response to or in connection with any discovery conducted in this litigation, and any copies, notes, abstracts or summaries of the foregoing materials.

(b) The designation of information as "Confidential" shall constitute a representation in accordance with Fed. R. Civ. P. 11 that such document, material or information has been reviewed and that there is a good faith basis for such designation. The provisions of Fed. R. Civ. P. 11 shall apply to any "Confidential" designation.

19(c) A party may not designate as "Confidential" information contained in documents which are already in the possession of a third party even if the documents contain information which would otherwise constitute Confidential Information, unless such documents were provided to the third party subject to the terms of a protective order entered by a court of competent jurisdiction. *§. pursuant to a writing requiring the information to be maintained in a confidential manner; or pursuant to statute.*

4. Designation of Confidentiality. Pursuant to paragraph 3 above, documents or information may be designated CONFIDENTIAL within the meaning of this Order in the following ways:

(a) In the case of documents and the information contained therein, designation shall be made by means of the following legend placed on each page of any such document: "CONFIDENTIAL" or "CONFIDENTIAL PURSUANT TO COURT ORDER."

(b) In the case of interrogatory answers, responses to request for admissions and the information contained therein, designation shall be made by means of a statement in the answers or responses specifying that the answers or responses or specific parts thereof are designated CONFIDENTIAL. The following legend shall be placed on the front of any set of interrogatory answers or responses to requests for admission containing Confidential Information: "CONTAINS CONFIDENTIAL INFORMATION."

(c) In the case of depositions and the information contained in depositions (including exhibits), designation of the portions of the transcript (including exhibits) which contain Confidential Information shall be made by a letter setting forth the specific pages and lines which disclose Confidential Information from counsel for the party or witness producing such information within thirty (30) days of receipt of the deposition transcript or copy thereof (or written notification that the transcript is available). During the deposition if such counsel makes a statement to the effect that the witness is disclosing Confidential Information the entire deposition transcript (including exhibits) shall be treated as Confidential under this Order until the expiration of the above-referenced thirty-day period for designation by letter, except that the deponent may review the transcript of his or other own deposition during this thirty-day period. The following legend shall appear on the first page of the transcript and each copy of the transcript containing Confidential Information: "CONTAINS CONFIDENTIAL INFORMATION." If part of a videotaped deposition is designated as CONFIDENTIAL, the videocassette or other videotape container shall be labeled with the legend provided for in paragraph 3(a) above.

(d) To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases or programs stored on any digital or analog machine-readable device, computers, discs, networks or tapes) ("Computerized Material") is produced by any party in such form, the producing party may designate such matters as CONFIDENTIAL by cover letter referring generally to such matter. Whenever any party to whom Computerized Material designated as CONFIDENTIAL is produced reduces such material

to hardcopy form, such party shall mark such hardcopy form with the legend provided for in paragraph 4 (a) above.

(e) To the extent that any party or counsel for any party creates, develops or otherwise establishes on any digital or analog machine-readable device, recording media, computers, discs, networks or tapes any information, files, databases or programs that contain information designated CONFIDENTIAL, that party and/or its counsel must take all necessary steps to insure that access to that electronic or magnetic media is properly restricted to those persons who, by the terms of this Order, may have access to Confidential Information.

(f) All documents and materials filed with the Court containing or reflecting the contents of Confidential Information shall be filed in sealed envelopes or other appropriate sealed containers on which shall be endorsed the caption to the Litigation, a generic designation of the contents, the words CONFIDENTIAL INFORMATION - SUBJECT TO COURT ORDER and words in substantially the following form:

This envelope contains documents which are filed under seal in this case by [name of party] and, by Order of this Court, dated ____, 200__, shall not be opened nor, the contents displayed or revealed except as provided in that order of by further order of the Court.

Any pleading or other paper required to be filed under seal pursuant to this Paragraph shall also bear the legend "FILED UNDER SEAL" in the upper-right hand corner of the cover page of the document. Only those portions of such documents and materials containing or reflecting Confidential Information shall be considered Confidential and may be disclosed only in accordance with this Order. Where possible, only those portions of such filings which are Confidential Information shall be filed under seal. No party or other person may have access to

any sealed document from the files of the Court without an order of the Court. The "Judge's Copy" of a sealed document may be opened by the presiding District Judge, the Judge's law clerks and other Court personnel without further order of the Court. Each document filed under seal may be returned to the party which filed it (1) if no appeal is taken, within ninety days after a final judgment is rendered, or (2) if an appeal is taken, within thirty days after the mandate of the last reviewing court which disposes of this litigation in its entirety is filed ("the final resolution of this litigation"). If the party which filed a sealed document fails to remove the document within the appropriate time frame, the document may be destroyed by the Clerk. Regardless of any provision in this Order to the contrary, a party does not have to file a document under seal if the Confidential Information contained or reflected in the document was so designated solely by that party, however, any such filing shall constitute a waiver of confidentiality for any documents, material or information contained in such a filing.

5. Use of ~~Discovery Materials~~ / [Confidential Information]. Any ~~Discovery Materials~~ / [Confidential Information] received by a party shall be used by that party solely for the purpose of conducting this litigation and shall in no event be used for any business, competitive, personal, private, public or other purpose, except as required by law. If the use of ~~Discovery Materials~~ / [Confidential Information] is required by law, the person using such information shall give notice to counsel for the producing party in accordance with paragraph 14 below. In no event shall any disclosure of Confidential Information be made to any competitor of any party, or to any person who, upon reasonable and good faith inquiry, could be determined to be an employee of any competitor of any party, irrespective of whether they are retained as an expert in this action.

6. Disclosure of Confidential Information. Access to information designated

CONFIDENTIAL pursuant to this Order shall be limited to:

- (a) counsel for the parties (including members or associates of such counsel's firm) or in-house counsel for the parties, as well as their paralegal, investigative, secretarial and clerical personnel who are engaged in assisting such counsel in this litigation;
- (b) outside photocopying, data processing or graphic production services employed by the parties or their counsel to assist in this litigation;
- (c) any outside expert, consultant or investigator who is not employed by or affiliated with any party or an affiliate of a party and is retained by counsel for the purposes of consulting, and/or testifying in this litigation, provided that paragraph 7 of this Confidentiality Order has been complied with;
- (d) any party or any director, officer or employee of a party charged with the responsibility for making business decisions dealing directly with the resolution of this action;
- (e) any person who authored or received the particular material sought to be disclosed to that person;
- (f) any person currently or formerly employed by the producing or receiving party if that person had regular access to the information contained in the particular confidential material sought to be disclosed to that person during the term of that person's employment with the party that produced or received the Confidential Material, provided that paragraph 7 of this Order has been complied with;

(g) deponents, trial or hearing witnesses and their counsel in preparation for and/or during deposition, trial or hearings, provided that paragraph 7 of this Order has been complied with;

(h) any Court exercising jurisdiction with respect to this litigation, Court personnel, jurors, alternate jurors, and qualified persons (including necessary clerical personnel) recording, taking or transcribing testimony or argument at any deposition, hearing, trial or appeal in this litigation;

(i) any other person to whom the party producing the information agrees in writing or on the record in advance of the disclosure, provided that paragraph 7 of this Order has been complied with.

7. Notification Of Protective Order. Confidential Information shall not be disclosed to any person described in paragraphs 6(c), 6(f), 6(g), or 6(i) unless and until such person has executed an Agreement of Confidentiality ("Agreement") in substantially the form attached hereto as Exhibit A. The originals of such Agreements shall be maintained by counsel for the party who obtained them until the final resolution of the litigation. Agreements shall not be subject to discovery except upon agreement of the parties or further order of the Court after application upon notice and good cause shown.

8. Objections to Designations. A party shall not be obligated to challenge the propriety of a Confidential Information designation at the time made, and a failure to do so shall not preclude a subsequent challenge thereto. The objection to the designation of information as "Confidential" shall constitute a representation in accordance with Fed. R. Civ. P. 11 that the objecting party has reviewed such document, material or information and that there is a good

faith basis for such an objection. The provisions of Fed. R. Civ. P. 11 shall apply to any such objection. Prior to applying to the Court for any relief, the objecting party shall consult with the designating party to attempt to resolve their differences. If the parties are unable to reach an accord as to the proper designation of the material, the objecting party may apply to the Court for a ruling that, the material shall not be so treated, giving notice to the party which has designated the material. If such a motion is made, the designating party would have the burden to establish that the designation is proper. If no such motion is made, the material will remain as designated. Any documents or other materials that have been designated Confidential shall be treated as Confidential until such time as the Court or any magistrate to whom this matter is assigned rules that such material should not be treated as Confidential.

9. Use of Confidential Information at Trial or Hearing. Unless otherwise directed by the Court, a party may, subject to the rules of evidence and further orders of the Court, use any Confidential Information for any purpose at trial or at any hearing before a judicial officer in this litigation.

10. Preservation of Rights and Privileges. Nothing contained in this Order shall affect the right, if any, of any party or witness to make any other type of objection, claim, or other response to discovery requests, including, without limitation, interrogatories, requests for admissions, requests for productions of documents or questions at a deposition. Nor shall this Order be construed as a waiver by any party of any legally cognizable privilege to withhold any Confidential Information, or of any right which any party may have to assert such privilege at any state of this litigation.

11. Return of Materials. Within forty-five (45) days after the final resolution of this litigation, all Confidential Information, including all copies, abstracts and/or summaries, shall be returned to counsel for the party that produced it or, if the producing party's counsel so requests, destroyed. As to those materials that contain or reflect Confidential Information, but that constitute or reflect counsel's work product, counsel of record for the parties shall be entitled to retain such work product in their files in accordance with the provisions of this Order, so long as it is clearly marked to reflect that it contains information subject to the Protective Order. Counsel shall be entitled to retain pleadings, affidavits, motions, briefs, other papers filed with the Court, deposition transcripts, and the trial record (including exhibits) even if such materials contain Confidential Information, so long as such Confidential Information, in accordance with the provisions of this Order, are clearly marked to reflect that they contain information subject to a Protective Order.

12. The inadvertent or unintentional disclosure by the producing party of Confidential Information, regardless of whether the information was so designated at the time of disclosure, shall not be deemed a waiver in whole or in part of a party's claim of confidentiality, either as to the specific information disclosed or as to any other information relating thereto or on the same or related subject matter. Upon learning of an inadvertent or unintentional disclosure of Confidential Information, the producing party shall within thirty (30) days designate such information as Confidential. The obligation to treat such information as Confidential shall run prospectively from the date of designation. Nothing contained within this paragraph prevents a party from challenging such a designation of documents or information pursuant to the procedures contained in paragraph 8.

13. A party's compliance with the terms of this Order shall not operate as an admission that any particular document is or is not (a) confidential, (b) privileged or (c) admissible in evidence at trial.

14. Any party or person who has been furnished with documents designated Confidential Information pursuant to this Order who receives a subpoena (or other process) from any person (including natural persons, corporations, partnerships, firms, governmental agencies, departments or bodies, boards or associations) who is not a party to this Order, which subpoena seeks productions or other disclosure of such Confidential Information, shall promptly and in any case by the close of the next business day give telephonic notice and written notice by overnight delivery or facsimile to counsel for the party who produced or designated the materials as confidential, identifying the material sought and enclosing a copy of the subpoena or other process. The party or person receiving the subpoena shall also inform the person seeking the Confidential Information that such Information is subject to this Order. No production or other disclosure of such information pursuant to the subpoena or other process shall occur before (a) ten (10) days following the date on which notice is given or (b) the return date of the subpoena. Notwithstanding this provision or any of the provisions herein, Defendants may disclose information contained in discovery materials that they receive in connection with this litigation consistent with their obligations to report adverse drug experiences pursuant to 21 C.F.R. 314.80.

15. Non-parties who are obliged in this litigation to provide discovery by deposition, production of documents or otherwise, may request the protection of this Order as to said non-party's own Confidential Information. The provisions of this Order shall be binding on the non-party requesting the protection of this Order.

16. Upon the final resolution of this litigation and/or each of the actions that comprise this litigation, the provision of this Order shall continue to be binding. This Court expressly retains jurisdiction over each of the actions that comprise this litigation for the purpose of enforcing the provisions of this Order following the final resolution of this litigation.

17. Documents, material and information designated as "Confidential" pursuant to the Protective Order entered in United States ex. rel. Franklin v. Parke-Davis, C.A. No. 96-11651-PBS (United States District Court for the District of Massachusetts)(the "Franklin Protective Order") may be disclosed to the persons identified in paragraph 6 of this Protective Order, subject to the terms and conditions provided herein. Paragraph 11 of the Franklin Protective Order, which provides that Confidential Information produced therein must be returned or destroyed within 45 days of the final resolution of that litigation, is superseded by Paragraph 11 of this Protective Order.

18. This Order is binding on all parties to this litigation and on all non-parties who have been served with a copy of this Order, and shall remain in force and effect until modified, superseded, or terminated by consent of the parties or by Order of the Court.

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SO ORDERED:

Dated: _____

1/10/05

Patti B. Saris

Hon. Patti B. Saris
United States District Judge